



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

APR 22 2004

Ilene Ringel Heller, Esq.  
Senior Staff Attorney  
Center for Science in the Public Interest  
1875 Connecticut Ave., NW, #300  
Washington, DC 20009

Re: Petition to Define the Terms "Low Carbohydrate," "Reduced Carbohydrate" and "Carbohydrate Free" and to Require Appropriate Statements to Accompany Such Claims to Prevent Consumer Deception

Dear Ms. Heller:

This letter acknowledges receipt on April 9, 2004, by the Food and Drug Administration (FDA) of your petition to establish nutrient content claims for carbohydrates and to require appropriate statements to accompany such claims to prevent consumer deception. This petition was submitted pursuant to Section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(A)(i)).

Your petition is currently undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the act (21 U.S.C. 343(r)(4)(A)(i)) and 21 CFR 101.69(m), within 100 days of receipt of a petition, the petition will either be filed for comprehensive review or denied. A denial may be either by FDA action within the 100-day period, which ends on July 18, 2004 or by a lack of action by FDA within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

2004P-0297

ACK1

Page 2 - Ilene Ringel Heller, Esq.

If you have any questions please feel free to contact Ritu Nalubola at (301) 436-2371.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Shellee Anderson", with a long horizontal flourish extending to the right.

Shellee Anderson  
Team Leader  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition